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Patent
Attorney's Docket No. 033388-371

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of)	Confirmation No. 1802
U.S. Patent No. 5,965,159)	
MAYHEW, et al.)	BOX REISSUE
Application No.: 09/976,936)	Group Art Unit: Unassigned
Filed: October 11, 2001)	Examiner: Unassigned
For: ETHERLIPID-CONTAINING)	
MULTIPLE LIPID LIPOSOMES)	

DECLARATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

We, Eric Mayhew, Andrew S. Janoff, Imran Ahmad, and Suresh Bhatia, the above-named inventors, hereby declare that:

1. I, Eric Mayhew, am a citizen of the United Kingdom, and my residence is 3905 West Bertuna Street, Seattle, Washington 98199;
I, Andrew S. Janoff, am a citizen of the United States, and my residence is 560 Countess Drive, Yardley, Pennsylvania 19067;
I, Imran Ahmad, am a citizen of India, and my residence is 4731 West Pebble Beach, Wadsworth, Illinois 60083;
I, Suresh K. Bhatia, am a citizen of India, and my residence is B-165 Sarita Vihar, Mathura Road, New Delhi 110044, India.

2. That we believe that we are the original and first inventors of the subject matter which is claimed in this application for reissue and for which reissue of the original Letters Patent on the invention entitled "ETHERLIPID-CONTAINING MULTIPLE LIPID LIPOSOMES" is sought.

3. That we have reviewed and understand the contents of the specification and claims of the above-identified reissue patent application, and that this specification and claims are attached to this declaration.

4. That we do not know and do not believe that said invention was ever known or used in the United States of America before our invention thereof.

5. That we acknowledge the duty to disclose to the Patent Office all information known to us to be material to the patentability of this reissue application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

6. That we believe the original patent to be partly inoperative or invalid by reason of claiming less than we had a right to claim in the patent. More specifically, such deficiencies in the claims include the failure to include a claim of the scope of new claim 17 which recites a liposome composition of a) a phosphatidylcholine b) a sterol c) a head group derivatized lipid and d) an etherlipid in which the Z component of the etherlipid of the claimed liposome may be an amine, an amide or a carboxylic acid. Support for these Z groups may be found at least at column 4, lines 22-26. Support for the phosphatidylcholine may be found at least at column 4 lines 55 - 59. Support for the sterol may be found at least at column 4 lines 60 - 67. Support for the head group derivatized lipid may be found at least at column 5 line 1 - column 6 line 52.

New dependent claim 18 recites a unilamellar liposome with a diameter of ~ 50 nm to ~ 200 nm. Support for unilamellar liposomes with this diameter may be found at least at column 3 lines 43 - 46.

New dependent claim 19 recites unsaturated or partially unsaturated phosphatidylcholine. Support for unsaturated or partially unsaturated phosphatidylcholine may be found at least at column 4 lines 55 - 58.

New dependent claim 20 recites that phosphatidylcholine is dioleoyl phosphatidylcholine. Support for dioleoyl phosphatidylcholine may be found at least at column 4 lines 58 - 59.

New dependent claim 21 recites that the sterol is cholesterol. Support for cholesterol may be found at least at column 4 lines 64 - 67.

New dependent claim 22 recites headgroup derivatized lipid that comprises a phosphatidylethanolamine selected from dipalmitoyl phosphatidylethanolamine, palmitoyloleoyl phosphatidylethanolamine or dioleoyl phosphatidylethanolamine. Support for these substances may be found at least at column 5 lines 16 - 21.

New dependent claim 23 recites that the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine. Support for dioleoyl phosphatidylethanolamine may be found at least at column 5 lines 19 - 20.

New dependent claim 24 recites that the headgroup derivatized lipid comprises a dicarboxylic acid selected from glutaric acid, sebacic acid, succinic acid or tartaric acid. Support for these groups may be found at least at column 6 line 41 - 52.

New dependent claim 25 recites that the dicarboxylic acid of claim 24 is glutaric acid. Support for glutaric acid may be found at least at column 6 line 44.

New dependent claim 26 recites that the headgroup derivatized lipid comprises dioleoyl phosphatidylethanolamine and glutaric acid. Support for these substances may be found at least at column 6 line 44 and column 5 lines 19 - 20.

New dependent claim 27 recites that the R_1 from Claim 17 is $(CH_2)_nCH_3$ and Z of claim 17 is $C(O)O$. Support for $C(O)O$ may be found at least at column 4 line 24.

New dependent claim 28 recites that the R_1 from Claim 17 is $(CH_2)_nCH_3$ and Z of claim 17 is NH . Support for NH may be found at least at column 4 line 22.

New dependent claim 29 recites that the R_1 from Claim 17 is $(CH_2)_nCH_3$ and Z of claim 17 is $HNC(O)$. Support for $HNC(O)$ may be found at least at column 4 line 22.

New dependent claim 30 recites an additional bioactive agent. Support for bioactive agents may be found at least at column 7 lines 16 - 57.

New dependent claim 31 recites pharmaceutical compositions based on the liposome of claim 17. Support for pharmaceutical compositions may be found at least at column 7 line 8 - 33.

7. That we believe the original patent to be partly inoperative or invalid due to typographical errors in the specification and in Claim 1. In Claim 1 (column 11 line 42) the letter "n" was omitted from in front of the number 8. Clearly this was a typographical error; the applicant intended to assign a value of either zero or 1 to the variable n_8 in the formula recited in claim 1. Likewise in the specification (column 4 line 8) the same correction was made. In addition, in the specification (column 3 line 66) the variable Y_1 was inadvertently assigned the designation y_1 . A cut up version of the Letters Patent is being submitted with these corrections included.

8. That the above identified reissue patent application was filed within two years of the issue date of the original patent and so broader claims than those in the issued patent are permissible.

9. That all errors being corrected in the above-identified reissue application arose without any deceptive intention on the part of the applicants.

10. That we hereby appoint the following attorneys to prosecute the presently filed reissue patent application and to transact all business in the Patent and Trademark Office connected therewith:

Gerald F. Swiss, Registration No. 30,113
Teresa Stanek Rea, Registration No. 30,427
Robert G. Mukai, Registration No. 28,531
Mary Ann Dillahunt, Registration No. 34,576
Mercedes K. Meyer, Registration No. 44,939
King L. Wong, Reg. No. 37,500
Ping F. Hwung, Reg. No. 44,164
Julie L. Heinrich, Registration No. 48,070
Kirsten A. Anderson, Reg. No. 38,813

Marilou E. Watson, Reg. No. 42,213
Kathleen M. Lunch, Reg. No. 33,957
James M. Hoch, Reg. No. 35,195
Jean M. Duvall, Reg. No. 32,731
Leslie J. Boley, Reg. No. 41,490

Address all correspondence to:

Gerald F. Swiss
Burns Doane Swecker & Mathis, LLP
P.O. Box 1404
Alexandria, Virginia 22313-1404


Address all telephone calls to Gerald F. Swiss at (650) 622-2300.

11. That we further declare that all statements made herein on our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Dated: 21/JAN/2002

By:


Eric Mayhew

By:

Andrew S. Janoff

By:

Imran Ahmad

By:

Suresh K. Bhatia



Patent
Attorney's Docket No. 033388-371

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3. That we have reviewed and understand the contents of the specification and claims of the above-identified reissue patent application, and that this specification and claims are attached to this declaration.

4. That we do not know and do not believe that said invention was ever known or used in the United States of America before our invention thereof.

5. That we acknowledge the duty to disclose to the Patent Office all information known to us to be material to the patentability of this reissue application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

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New dependent claim 24 recites that the headgroup derivatized lipid comprises a dicarboxylic acid selected from glutaric acid, sebacic acid, succinic acid or tartaric acid. Support for these groups may be found at least at column 6 line 41 - 52.

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Respectfully submitted,

Dated: _____

By: _____
Eric Mayhew

By: _____
Andrew S. Janoff

By: Imran Ahmad
Imran Ahmad

By: _____
Suresh K. Bhatia



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In re Reissue Application of:)
Eric MAYHEW *et al.*) Group Art Unit: 1615
for U.S. Patent No. 5,965,159) Examiner: Unassigned
Reissue Application No.: 09/976,936)
Filed: October 11, 2001)
For: ETHERLIPID-CONTAINING)
MULTIPLE LIPID LIPOSOMES)

DECLARATION OF
TERESA STANEK REA

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

1. I, Teresa Stanek Rea, declare and state as follows:
2. That I reside at 9417 Mt. Vernon Circle, Alexandria, Virginia, 22309.
3. I understand that the invention which gave rise to this reissue patent application was developed by the following inventors: Eric Mayhew, Andrew Janoff, Imran Ahmad and Suresh Bhatia. Andrew Janoff has not signed the Declaration and Power or Attorney document.
4. The evidence supporting the assertion that Andrew Janoff will not sign the Declaration Power or Attorney document, despite dilligent efforts to make him sign, is as follows:
 - a. On December 28, 2001, the Declaration and Power of Attorney form, along with a copy of the reissue patent application as filed, were sent to Andrew Janoff via Certified Mail to his home in Yardley, Pennsylvania. A copy of the stamped Certified Mail receipt is enclosed herewith

as Exhibit A, showing that the application and documents were received and signed for by Andrew Janoff on January 3, 2002.

b. I spoke via telephone with Andrew Janoff at least three times concerning the need for him to sign the Declaration and Power of Attorney form. On April 5, 2002, I held a further telephone conference with Andrew Janoff regarding executing the Declaration and Power of Attorney form. Andrew Janoff indicated that he would be out of the country and that he would review and sign the forms early May.

c. On May 1, 2002, another copy of the application and the Declaration and Power of Attorney form were sent to Andrew Janoff at the Yardley, Pennsylvania address via Federal Express. A copy of the Federal Express Airbill is enclosed herewith as Exhibit B.

d. On May 10, 2002, I called Dr. Janoff's home and left a message with his wife or daughter regarding the Declaration and Power of Attorney form and requested that he contact me.

e. On May 13, 2002, Deborah Yellin of Burns Doane Swecker & Mathis called Dr. Janoff's home and left a message on the answering machine regarding the status of the Declaration and Power of Attorney.

f. On May 28, 2002, I called Dr. Janoff's home and left a telephone message with his wife or daughter the answering machine regarding the Declaration and Power of Attorney form. As of this date, Dr. Janoff has not returned any of my telephone inquiries.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

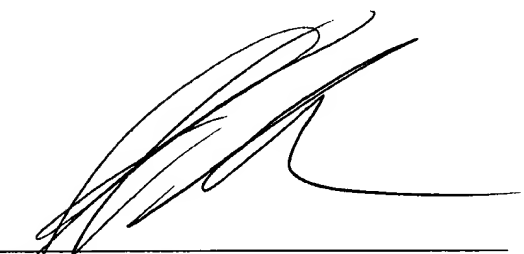
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Date:

July 1, 2002

By:


Teresa Stanek Rea